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EXAMINER

BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
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1626

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07/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

In view of Applicant's Response and Amendments, filed 06/24/2010, claims 1 and 7-25 remain pending in this Application.

Response to Remarks

Obviousness-Type Double Patenting: Regarding the rejections of claims 1 and 7-25 over Application 11/847593 (now issued, US 7750001) and US 7307077, Applicant points out the '593 Application was amended prior to issuance, and these amendments obviate the rejection over this Application (now US 7750001). The 7750001 Patent does not render Applicant's claims 1 and 7-25 obvious, and this rejection is withdrawn.

Additionally, Applicant argues the US 7307077 do not render claims 1 and 7-25 obvious, since the '077 Patent requires -OH where Applicant's claims require -OY, wherein Y is not H. Applicant points out the substitution of an alkoxy for the hydroxy shown in the '077 Patent produces significant differences in chemical properties. These differences are illustrated by Tables 1,2, and 3 in the Specification at pp. 17-19. Moreover, Applicant notes the use of the '593 Application as an evidentiary reference is improper. In light of these arguments, US 7307077 does not render Applicant's claims 1 and 7-25 obvious, and this rejection is also withdrawn.

35 USC 112, second paragraph: Applicant amended claims 22-25, changing "tumor cell" to "cancer cell" in order to correspond with the language used in claim 21.

Accordingly, this rejection is moot and withdrawn.

35 USC 112, first paragraph: Applicant argues claims 21-25 possess adequate enablement. In support of this argument, Applicant filed an article: Yaguchi, et al. *J. Natl. Cancer Inst.* 98:545 (2006). The article demonstrates PI3K inhibition utilizing a compound having a similar core as Applicant's claimed genus. Yaguchi also demonstrates the growth inhibition activity of this compound against 39 human cancer cell lines corresponding to breast, CNS, colon, lung, melanoma, ovarian, renal, stomach, and prostate cancers.

Applicant argues the claimed compounds demonstrate inhibition of the growth of human colon cancer cells *in vitro* and *in vivo*. Indeed, this much was acknowledged and stated in the previous Office Action. Applicant goes on to argue no reason has been presented as to why the skilled artisan could not extrapolate to all types of cancer cells this *in vitro/in vivo* correlation, as shown in the Yaguchi reference.

Applicant is reminded the rejected claims are not drawn toward treatment of specific cancers but rather a method of inhibiting the growth of any cancer cell (claim 21), any human tumor cell (claim 22), any solid human tumor cell (claim 23), which is done *in vivo* (claim 24), and finally a human colon cancer cell, lung cancer cell, breast cancer cell, or prostate cancer cell (claim 25). Applicant's reliance on Yaguchi tends to indicate that the growth of specific cancers may be inhibited by structurally similar compounds to those claimed by Applicant. For this reason, the rejection against claim 25 is withdrawn, meaning claim 25 would only be objected to for dependence on a rejected base claim.

As to claims 21-24, the rejection would be maintained or reapplied. Essentially, there is not enough guidance in the literature to support Applicant's claim to inhibiting the growth of all types of cancer cells. While there is certainly a correlation shown between Applicant's compounds and inhibition of the growth of certain types of solid tumor cells, this correlation is not strong enough such that demonstration of a few, specific growth inhibition activities is representative of growth inhibition of all cancer cells. Accordingly, the claims, as currently presented, may be summarized as follows:

Claims 1 and 7-20: ALLOWED

Claims 21-24: REJECTED (35 USC 112, 1st)

Claim 25: OBJECTED TO.

Conclusion

Any questions about this Office Action may be directed toward Examiner Michael Barker at 571.272.0303. If, however, attempts to reach Mr. Barker are not successful, the Examiner's supervisor, Joseph McKane, may be reached at 571.272.0699.

/MICHAEL BARKER/
Examiner, Art Unit 1626